

### **REMARKS**

Claims 1, 2, 4-12, 14, 15, 17, 19 and 21-41 are pending in the current application. Claims 4, 14, 15, 19 and 21 have been canceled. Claim 1 has been amended to specify the first crystalline form of riboflavin as riboflavin dihydrate and the specific amount of DNA in the riboflavin crystals of step (d) as below 0.2 parts per billion. Support for this amendment may be found throughout the specification, for example, page 3, paragraph [0040], original claim 4 and page 6, paragraph [0065]. It is believed no new matter has been added.

### **Restriction Requirement**

The examiner issued a five-way restriction, claiming that Groups I-V “are drawn to independent or distinct inventions that requires distinct searches” because “each of the above claimed inventions contains one or more patentably distinct process steps. *Office Action*, 12/23/2008, p. 4.

Applicants respectfully traverse. The current application is a national phase application of PCT/EP04/08097. As such, MPEP 1893.03(d) provides that “unity of invention (not restriction practice pursuant to 37 CFR 1.141 - 1.146) is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371.”. The unity of invention standard does not require that the claims be drawn to a single invention; only that the claims be linked by a single general inventive concept. *See* PCT Rule 13; 37 C.F.R. §1.475; MPEP 1850. MPEP 1893.01(d) also provides that “[a] group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature.” *Id.* “Special technical feature” is defined as “those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” *Id.* Here, the claims all involve the single general inventive concept relating to the process for the purification of riboflavin from DNA impurities, which process is novel and non-obvious over the prior art comprising the step of transforming a first crystalline form of riboflavin into a second crystalline form of riboflavin. As such, the current inventions satisfy the unity of invention requirement and restriction requirement is not proper.

Even if there is no unity of invention among all of the claims, the restriction should at most be a three-way restriction (Groups I and V; Groups II and III; and Group IV) rather than a five-way restriction. The invention of Group I and Group V both belong to the same classification, e.g., Class 435, subclass 262 and therefore do not require a different field of search. Both Groups I and V involve removing DNA from fermentatively produced riboflavin comprising transforming the first crystalline form of riboflavin into a second crystalline form of riboflavin and therefore have overlapping scope. The prior art applicable to one invention would likely to be applicable to another invention. The inventions are not likely to raise different non-prior art issues under 35 U.S.C. § 101 and/or § 112, first paragraph. As such, there is no serious burden on the Examiner if restriction is not required.

Similarly, Group II and Group III both belong to the same classification, namely class 544, subclass 251. Both groups involve a process for the purification of riboflavin comprising three identical steps out of four steps and therefore have overlapping scopes. Both groups are linked by the single general inventive concept of purification of riboflavin comprising transforming one crystalline form to another. The field of search should be the same and should not raise any serious burden on the Examiner that would necessitate a restriction requirement between the two groups.

For the reasons stated above, Applicants respectfully request reconsideration and withdrawal of the restriction requirement. In the event that the Examiner maintains the Restriction Requirement, and reserving all rights, including the right of reinstatement or rejoinder in the event the restriction requirement is withdrawn or a generic claim is allowed, and/or the right to pursue any non-elected inventions in divisional applications, Applicants provisionally restrict, with traverse, to Group I, claims 1-2, 4-12, 14-15, 17, 19 and 21.

While claim 1 is currently amended, it is noted that the amendment does not affect the arguments Applicants made herewith as all of the claims still involve the single general inventive concept relating to the process of purifying riboflavin from DNA impurities, which process comprising the step of transforming a first crystalline form of riboflavin into a second crystalline form of riboflavin. For reasons stated above, Applicants respectfully request for reconsideration and withdrawal of the restriction requirement.

Election of Species


In addition to restriction requirement, the Examiner also required Applicants to elect a single disclosed species for prosecuting on the merits.

As a primary matter, Applicants thank the Examiner for taking the time on January 16, 2009 to speak with Applicants' attorney, clarifying the election of species. The Examiner clarified that Applicants are required to elect one species from each of the listed groups A-D. Applicants therefore provisionally elect the following species for search purposes only: A) the first crystalline form of riboflavin to be (aii) riboflavin dihydrate; B) the second crystalline form of riboflavin to be (a) riboflavin anhydrate I; C) the condition for transforming the first form of riboflavin to a second form of riboflavin is mineral acid; and D) the riboflavin is produced or obtained by fermentation.

The Examiner argued that the election is required for prosecution on the merits because the species are mutually exclusive, require a different field of search, raise different prior art issues and that prior art applicable to one would not likely to be applicable to another. Applicants respectfully disagree. The different forms of riboflavin are not mutually exclusive per se as they are all riboflavin, whether in one form or another, and one crystal form may be transformed to another crystal form depending on the conditions (e.g., pH, temperature) of the broth/solution/slurry. As such, it is unlikely that the field of search would be different or that the prior art applicable to one would not be applicable to another so as to raise an examination and search burden on the Examiner. Applicants therefore respectfully request withdrawal of the election of species for prosecution on the merits. In the event that the Examiner maintains the election requirement and the generic claims are allowed, Applicants reserve the rights for the Examiner's "consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141."

Respectfully submitted,

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